

REMARKS

Claim 4 has been amended to delete “for a period of time sufficient to reduce sagging.” Claim 20 has been amended to delete “for a period of time sufficient to allow the breast to absorb a sufficient quantity of L-arginine to produce a smoother surface in the breast,” and “replace L-arginine with “L-arginine hydrochloride.” Support can be found in the specification, for example, on page 6, line 12.

Claims 2-4, 7-10, 12, 14, 15, 20-23, and 27-30 are currently pending for examination. Claims 4, 20, and 29 are independent.

Rejections under 35 U.S.C. § 103(a) in view of Fossel and Falk

Claims 3, 4, 7-10, 12, 14, 15, 19-23, and 27-29 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Fossel, U.S. Pat. Apl. Pub. No. 2003/0028169 (“Fossel”) in view of Falk, *et al.*, U.S. Pat. No. 5,824,658 (“Falk”).

The limitations “for a period of time sufficient to reduce sagging” and “for a period of time sufficient to allow the breast to absorb a sufficient quantity of L-arginine to produce a smoother surface in the breast” have been deleted from claims 4 and 20, respectively, thus mooted the comments in the Office Action regarding these limitations. No concession is made as to the accuracy of the Examiner’s comments.

With respect to independent claim 29, the Examiner has still failed to identify a specific teaching or suggestion in either Fossel or Falk of applying a composition to a subject diagnosed as having breast ptosis by rubbing the composition into the breast. Claim 29 *specifically* recites breast ptosis as a medical condition that is to be *diagnosed*, e.g., by a qualified medical clinician. The Examiner must identify a specific teaching or suggestion of treatment of breast ptosis in the prior art, as is required for a finding of obviousness. “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), quoting *In re Kahn*, 441 F.3d 977 (Fed. Cir. 2006); see also M.P.E.P. § 2143.01.

Furthermore, the Examiner continues to be unable to identify a location in either Fossel or Falk that teaches or suggests rubbing a delivery vehicle into the breast, as is specifically recited in

each of independent claims 4, 20, and 29. Instead, the Examiner appears to be of the position that the reason it would have been obvious to rub the delivery vehicle into the breast is because “the skin covering the human breast has substantially the same anatomical and morphological structure as other parts of the skin,” and the fact that the Applicant recognized another advantage that would “flow naturally” from following the suggestion of the prior art cannot be the basis for patentability. (See section 8 of the Office Action.)

The burden is on the Examiner to set forth a *specific* rationale as to why one of ordinary skill in the art would have found the claimed invention to have been obvious. Although the Examiner states that the delivery vehicle is “capable” of being applied to the breasts, such a rationale does not explain why one of ordinary skill in the art would have been motivated to apply the delivery vehicle to the breasts, or would have found it obvious or predictable that the method would reduce breast sagging. The mere fact that references are “capable” of being modified or combined does not render the resultant combination obvious unless the results would have been obvious or predictable to one of ordinary skill in the art. See, e.g., *KSR* or M.P.E.P. § 2143.01(III). The Examiner has not demonstrated that either Fossel or Falk discloses or suggests actually applying a delivery vehicle to the breasts; instead, the Examiner alleges that a specific rationale is unnecessary for him to provide because such a conclusion would “flow naturally” from Fossel and Falk. But for the reasons discussed below, such a conclusion of applying the delivery vehicle to the breasts is not consistent with the teachings of Fossel or Falk.

In particular, Fossel teaches that his composition is useful for wound healing (e.g., of ulcers to the legs or limbs), increasing erectile function, and increasing growth of hair. See, e.g., the Abstract, paragraphs 0003, 0008, or 0009-0016, or Examples 1-3 of Fossel. None of these indications reasonably suggests that one of ordinary skill in the art could apply a delivery vehicle to the breast with an expectation of the same or similar results. In addition, the results that are actually achieved—causing the breasts to appear fuller and/or raised—would have been unexpected based on these teachings of Fossel and Falk.

The breast is clearly not the same thing as a limb, i.e., a leg or arm. Accordingly, it is not reasonable to suggest that applying the delivery vehicle to the breast would “flow naturally” from a treatment of an ulcer located on an arm or leg.

The breast also does not grow hair. Thus, the statement in the Office Action that the skin covering the human breast has substantially the same anatomical and morphological structure as other parts of the skin is actually incorrect (section 8, last paragraph on page 2 of the Office Action). Moreover, the Patent Office has not set forth any reasonable explanation as to why one of ordinary skill in the art (or anyone else) would want a hairy breast.

The breast is also clearly not the penis. Accordingly, the treatment of erectile dysfunction in a male has no relevancy to the treatment of a breast in a female. Applying a delivery vehicle to the breast would not “flow naturally” from the teaching of applying a delivery vehicle to the penis in Fossel—*it’s the wrong gender*.

Falk appears to have been cited only for the proposition that rubbing a cream would “improve therapeutic effect to the treatment” (section 8, last paragraph on page 2 of the Office Action). But that statement does not provide any explanation as to why one of ordinary skill in the art would apply the cream to the *breast*. Accordingly, Falk does not appear to have been cited for the proposition of applying a delivery vehicle to the breast.

“[W]hen design need and market pressure may dictate a commonsensical path using a finite number of identified predictable solutions to one of ordinary skill, deviations from that path are likely products of innovation.” *Unigene Laboratories, Inc. v. Apotex, Inc.*, ___ F.3d ___ (Fed. Cir. 2011). The references cited by the Examiner might justify treatments relating to ulcers, hair growth, or erectile dysfunction, or related indications, but treating a breast to cause the breast to appear fuller and/or raised is a substantial deviation from that path, and is not supported by either Fossel or Falk.

In addition, submitted herewith is a declaration from the inventor of the present application, Eric T. Fossel, explaining the differences between the presently claimed invention and the cited prior art references, as well as providing secondary considerations that should also be taken into account. In particular, the declaration provides support for commercial success of the presently claimed invention, and evidence of copying in the form of a licensing agreement by another company interested in selling a product embodying the presently claimed invention. Furthermore, other products embodying the earlier Fossel reference, directed to treatment of hair growth and erectile dysfunction, have been independently commercially successful, thereby demonstrating that

a breast enhancement cream is not easily confused with creams for growing hair or treating erectile dysfunction, and suggesting that a breast enhancement cream is not obvious or predictable in view of a cream for growing hair or treating erectile dysfunction. Such evidence of secondary considerations further supports the Applicant's position that the claimed invention would not have been obvious in view of Fossel or Falk.

Under *KSR*, the burden is on the Examiner to provide an articulate reason with some rational underpinning as to why one of ordinary skill in the art would make the proposed combination. The Examiner has not identified a location in either Fossel or Falk that specifically teaches applying a delivery vehicle to the breast. The rationale that the Examiner gives—that it would “flow naturally” from Fossel and Falk—would not be a reasonable conclusion to draw by a person of ordinary skill in the art, as it would suggest that the breast and the penis or a leg are the same, or that a person of ordinary skill in the art would want hairy breasts. Such conclusions are plainly irrational, and cannot be used to support an obviousness rejection. Thus, it is respectfully requested that the rejection of claims 3, 4, 7-10, 12, 14, 15, 19-23, and 27-29 be withdrawn.

Rejections under 35 U.S.C. § 103(a) in view of Fossel, Falk, and Nakata

Claim 2 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Fossel in view of Falk, and further in view of Nakata, *et al.*, U.S. Pat. No. 5,332,758 (“Nakata”).

Claim 2 depends from claim 4. For at least the reasons explained above with respect to the rejection under § 103(a) in view of Fossel and Falk, the premise of the rejection of claim 4 (that the combination of Fossel and Falk teaches all of the limitations of claim 4) is believed to be incorrect. Accordingly, while Applicant does not concede that there would have been any rational reason to combine Fossel, Falk, and Nakata in the manner suggested in the Office Action, the present rejection cannot stand, regardless. Thus, withdrawal of the rejection of claim 2 is respectfully requested.

CONCLUSION

Favorable action is respectfully requested. If, for any reason, the Examiner is of the opinion that a telephone conversation with the Applicants' representative would expedite prosecution, the Examiner is kindly invited to contact the undersigned at the number below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, any necessary extension of time is hereby requested. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. S1509.70037US01, from which the undersigned is authorized to draw.

Dated: April 9, 2012

Respectfully submitted,

By Tani Chen
Tani Chen, Sc.D.
Registration No.: 52,728
Patrick R.H. Waller, Ph.D.
Registration No.: 41,418
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
617.646.8000